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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/840,197	04/23/2001	Abe Widra	383939.00002	5490

7590 09/26/2003

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EXAMINER

SAUCIER, SANDRA E

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 09/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/840,197	WIDRA, ABE	
	Examiner	Art Unit	
	Sandra Saucier	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 9-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>6, 11</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1–20 are pending. Claims 1–8 are considered on the merits. Claims 9–20 are withdrawn from consideration as being drawn to a non-elected invention.

Election/Restriction

Claims 9–20 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected, the requirement having been traversed in Paper No. 5.

Upon the determination of an allowable composition, applicants may submit method of use claims limited to the allowable composition which will also be allowed if they do not present new matter and are definite.

The traversal is directed to alleged absence of burden since the search for one group would encompass all groups. First, the methods are distinct and a search for an intravenous administration is not the same as a search for a method of perfusion of an isolated organ, for example. It is highly unlikely that applicant would accept a reference teaching a method of intravenous administration of keratose as being anticipatory over a method of perfusion of an isolated organ. A statement by applicant on the record that a reference that makes one group obvious or anticipated would be accepted as making all the groups anticipated or obvious might permit regrouping of the claims. Second, burden is found not only in the search, but in the prosecution of multiple inventions.

Claim Rejections – 35 USC § 112

INDEFINITE

Claims 2, 4–6 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 2 ,4, 6 and 8 there is no antecedent basis for "the solvent". Only one "and" should be in a Markush group.

In claim 5, the preamble (a pharmaceutically acceptable carrier) and in claim 7 (a buffer) is not read as a component of the solution. If applicant, for example, wishes to claim a solution comprising alpha keratose and a pharmaceutically acceptable carrier, both components should be in the body of the claim.

Claim Rejections – 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action: A person shall be entitled to a patent unless (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent, (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 5 and 7 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by JP 08-332087 [N].

The claims are directed to a solution of α -keratose.

The references are relied upon as explained below.

JP 08-332087 discloses a solution of α -keratose.

Claims 1-8 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Ewald *et al.* [IDS].

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Ewald *et al.* disclose a composition comprising a soluble component of keratin obtained by hydrogen peroxide hydrolysis in sterile saline. α -keratose would at least be one component of the solution disclosed by Ewald *et al.*

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651. The supervisor for 1651 is M. Wityshyn, (703) 308-4743. The normal work schedule for Examiner Saucier is 8:30 AM to 5:00 PM Monday and Tuesday and 8:30 AM to noon on Wednesday.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (703) 308-1084. Status inquiries must be directed to the Customer Service Desk at (703) 308-0197 or (703)-308-0198. The number of the Fax Center for the faxing of official papers is (703) 872-9306 or for after finals (703) 872-9307.

A handwritten signature in black ink, appearing to read 'Sandra Saucier', with a stylized, cursive script.

Sandra Saucier

Primary Examiner

Art Unit 1651

September 25, 2003